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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,834	03/16/2004	Steven M. Ruben	PZ029P1D3	2119

22195 7590 10/13/2006

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EXAMINER	
HAMUD, FOZIA M	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/800,834	RUBEN ET AL.	
	Examiner	Art Unit	
	Fozia M. Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 14-15, 24 drawn to an isolated nucleic acid molecule comprising a polynucleotide sequence set forth in SEQ ID NO:40, a vector comprising said nucleic acid, a host cell comprising said nucleic acid molecule and a method of producing a polypeptide, classified in class 435, subclass 69.1.

II. Claims 11-12, 16, drawn to an isolated polypeptide comprising an amino acid sequence as shown in SEQ ID NO:161, classified in class 530, subclass 350.

III. Claim 13, 26 drawn to an antibody, which selectively binds to a polypeptide, classified in class 530, subclass 389.1.

IV. Claim 17 drawn to a method for preventing, treating or ameliorating a medical condition by administering an effective amount of polypeptide, class 514, subclass 2.

V. Claim 18 drawn to a method for preventing, treating or ameliorating a medical condition by administering an effective amount of polynucleotide, class 514, subclass 44.

VI. Claim 19 drawn to a method for preventing, treating or ameliorating a medical condition by administering an effective amount of antibody, class 514, subclass 12.

VII. Claim 20, drawn to a method of diagnosing a pathological condition by determining the presence or absence of a mutation in a polynucleotide, classified in class 435, subclass 6.

VIII. Claim 21, 22, drawn to a method of diagnosing a pathological condition by determining the presence or absence or expression of a polypeptide, classified in class 435, subclass 9.1.

IX. Claims 23, 25, drawn to a method to screen for compounds that modify a polypeptide, classified in class 435, subclass 7.2.

The inventions are distinct, each from the other because of the following reasons:

The polypeptide of Group II and nucleic acid of Group I are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and nucleic acids, which are composed of purine and pyrimidine units, are structurally distinct molecules, any relationship between a nucleic acid and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a nucleic acid of Group I does not necessarily encode a polypeptide of Group II. For example, the information provided by the nucleic acid of Group I can be used to make a materially different polypeptide than that of Group II. Furthermore, a nucleic acid which hybridizes to SEQ ID NO: 40, even under stringent conditions, encompasses molecules which contain point mutations, splice sites, frame shift mutations or stop codons which would result in use of a different open reading frame, and thus encode a protein that lacks any significant structure in common

with SEQ ID NO. 161. In addition, while a polypeptide of Group II can made by methods using some, but not all, of the nucleic acid that fall within the scope of Group I, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of Groups I and II are patentably distinct. Furthermore, searching the inventions of Groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the nucleic acids are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. The databases used to search the sequences of polypeptides are not the same databases used to search nucleic acid sequences. As such, it would be burdensome to search the inventions of Groups I and II together. The polypeptide of Group II and the antibody of Group III are patentably distinct for the following reasons: While the inventions of both Group II and Group III polypeptides, in this instance the polypeptide of Group II is a single chain molecule that functions as an cytokine, whereas the polypeptide of Group III encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of Group II and the antibody of Group III are structurally distinct molecules, any relationship between a polypeptide of Group II and an antibody of Group III is dependent upon the correlation between the scope of the polypeptides

that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide. Furthermore, searching the inventions of Group II and Group III would impose a serious search burden. The inventions have a separate status in the ad as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of Group III. Furthermore, antibodies which bind to an epitope of a polypeptide of Group II may be known even if a polypeptide of Group II is novel. In addition, the technical literature search for the polypeptide of Group II and the antibody of Group III are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The nucleic acid of Group I and the antibody of Group III are patentably distinct For the following reasons. The antibody of Group III includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of Group III which are composed of amino acids, and nucleic acid, which are composed of nucleic acids, are structurally distinct molecules, any relationship between a nucleic acid and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a nucleic acid of Group I will not

encode an antibody of Group III, and the antibody of Group III cannot be encoded by a nucleic acid of Group I. Therefore the antibody and nucleic acid are patentably distinct. The antibody and nucleic acid inventions have a separate status in the ad as shown by their different classifications. Furthermore, searching the inventions of Group I and Group III would impose a serious search burden since a search of the nucleic acid of Group I would not be used to determine the patentability of an antibody of Group III, and vice-versa.

Inventions II is related to inventions IV, VI and VII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II can be used in a process of raising antibodies that bind to it. Searching the inventions of Groups II, IV, VI and VII together would impose serious search burden. The inventions of Groups II, IV, VI and VII have a separate status in the art as shown by their different classifications.

Inventions I and III are unrelated to inventions IV, VI or VII, because none of the products of groups I and III are used or otherwise involved in the processes of groups IV, VI or VII.

Inventions I is related to inventions V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Group I can be used in a process of producing the encoded polypeptide. Searching the inventions of Groups I and IV together would impose serious search burden. The inventions of Groups I and V have a separate status in the art as shown by their different classifications.

Inventions II and III are unrelated to inventions V, because none of the products of groups II and III are used or otherwise involved in the process of group V.

The inventions of Groups I, II, III, IV, V, VI and VII have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search any combination of the inventions of Groups I, II, III, IV, V, VI or VII together.

Inventions IV, V, VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of detecting a nucleic acid (group V), the method of detecting a polypeptide (group VI), the method of using a polypeptide for screening compounds, (VII) and the method of treating a condition by using a polypeptide (group IV) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for detecting a polypeptide differs significantly

from one that detects a nucleic acid, which also differs significantly from a method of treating a condition. Therefore, each method is divergent in materials and steps. For these reasons the Inventions IV, V, VI and VII are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups IV, V, VI and VI have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups IV, V, VI and VI together. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has prima facie shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

2. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fozia Hamud
Patent Examiner
Art Unit 1647
03 October 2006

Eileen B. O'Hara

EILEEN B. O'HARA
PRIMARY EXAMINER